



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration  
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Denver, Colorado 80225-0087  
Telephone. 303-236-3000  
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December 5, 2000

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Alex A. Kropf, President  
Arctic Pacific Fisheries, Inc.  
3910 W. Colfax Ave.  
Denver, CO 80204

Ref. # : DEN-01-12

Dear Mr. Kropf:

We inspected your firm, located at the above address, on July 24 - 30, 2000 and found that you have serious deviations from the Seafood HACCP regulations [Title 21 Code of Federal Regulations, Part 21 (21 CFR Part 123)]. These deviations cause your fresh and vacuum packed fish products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, at the time of the inspection, your firm did not have an adequate HACCP plan for cold smoked salmon to control the safety hazard of *Clostridium botulinum*. Specifically, the document titled "Cold Smoking Flow Chart", which you identified as your HACCP plan in effect at the time of the inspection, is inadequate as it did not describe the actual process in use nor did it include hazards and critical limits; monitoring and verification procedures; or corrective actions. We note that during the inspection you provided the Investigator with a draft copy of a new HACCP plan to correct the above deficiency. You also informed the Investigator that you would submit the final version of this HACCP plan with your written response to the inspection. As of this date, we have not seen a written response from you.

You must implement a recordkeeping system that documents the monitoring of the critical control points that contain the actual values and observations obtained during monitoring, to

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comply with 21 CFR 123.6(c). However, your firm did not record or accurately record monitoring observations at several critical control points to control *Clostridium botulinum*. For example:

On 7/24, 25 and 26/2000, monitoring records for brining, drying, dry curing, smoking, trimming and slicing were not recorded at all. Additionally, you informed the Investigator that you require the employee to complete this monitoring record at the end of the day so he does not have to stop his work to fill out the form and then wash his hands to begin work again. Since the employee is required to record the beginning and ending time and temperature for each step, the accuracy of the values recorded are questionable if they are recorded only at the end of the day. Further, the employee does not record the actual time the temperatures are taken, nor is the complete date recorded on the documents.

Monitoring records for cold smoked processing of salmon and chum do not include specific dry cure critical factors (i.e., ratio of salt, sugar and nitrites to fish); size of fish processed; or smoker temperature.

Monitoring of refrigeration temperatures, a critical control point for your hot smoked vacuum packaged fish with a critical limit of 38° F, is inadequate in that monitoring is only performed ~~2~~ days per week and actual times are not recorded. Review of monitoring records during the inspection noted the small refrigerator temperature on Friday afternoon, 7/21/2000, was reported at 38° F and on Monday morning, 7/24/2000, at 42° F. It can not be determined how long product was exposed to temperatures above 38° F

You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm does not verify the adequacy of several critical control limits. For example:

Water Phase Salt Testing of smoked salmon (lox) has only been performed (~~XX~~) in the last year (~~XXXX~~). There is no record of the size/weight of the fish tested. This is inadequate to assure all of your smoked fish products consistently meet acceptable water phase salt levels. You must test all of your smoked fish products on a periodic basis to verify the effectiveness of your process. We note that the test results dated (~~XXXX~~) included a second product - Pastrami salmon. The water phase salt level is reported as 2.91%, which appears to be a failure in your brining process. In your response to this letter, please explain this low water phase salt level and what actions you took as a result of this lab report.

There is no record of calibration for the standard (digital) thermometer.

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Monitoring records for the critical control points of cold smoke processing and refrigerator/freezer temperatures are not reviewed as evidenced by lack of reviewer signature and date.

You must correct sanitation deficiencies detected during monitoring in a timely manner, to comply with 21 CFR 123.11(b). The following sanitation deficiencies were noted during the inspection:

Several live and dead insects (German Cockroaches) were observed on the floors and walls in both processing rooms, and on the inside of the door to the hot smoker.

On 7/25/00, a salmon fillet was observed to fall out of a brining barrel on to the concrete floor. The fillet was then placed on the table and processed.

A backflow prevention device was not installed on the threaded faucet in the brine processing room which had a hose attached, the end of which was lying on the floor.

The handsink located directly outside the toilet room does not have a mixing valve to allow for proper handwashing.

The ceiling in the processing area is in disrepair with gaps and portions sagging.

Ceiling and walls throughout the facility were soiled with a yellow film.

We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

During the inspection, our Investigator observed the use of a solution of Zep FS Amine-B Sanitizer (quaternary ammonium chloride) and water (measured at 200 ppm on 7/25/2000) as a "screen dip" on raw salmon intended to be cold smoked. The product labeling states for use on food processing equipment and other hard surfaces only. For your information, there is no regulation in effect allowing for the safe use of this chemical sanitizer on salmon. We request that you submit the information and evidence you used to determine that the use of this chemical sanitizer is safe when used in this manner.

**This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.**

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to

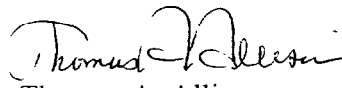
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include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please direct your response to the Food and Drug Administration, Attention: Mr. Tom Warwick, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Warwick at (303) 236-3054.

Sincerely,

  
Thomas A. Allison  
District Director

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